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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,238	09/12/2003	Rene Verdonk	920522-94798	6848

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EXAMINER
ALI, SHUMAYA B

ART UNIT	PAPER NUMBER
3743	

DATE MAILED: 08/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/661,238	VERDONK ET AL.	
	Examiner	Art Unit	
	Shumaya B. Ali	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 May 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) *7,13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8-12 and 14-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *9/12/03* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

In response to the office action mailed on 5/18/06 the Applicant has amended claims 1-3,5,6,11. Currently claims 1-6,8-12, and 14-18 are pending in the current application.

Allowable Subject Matter

Objection to claims 2 and 12 as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims is withdrawn due to amendment filed on 5/18/06

Response to Arguments

Applicant's arguments filed 5/18/06 have been fully considered but they are not persuasive. Regarding non-statutory subject matter Applicant argues Applicant is not claiming a person's limb (see remark page 5, lines 6-8), but rather a device that provides motion to a limb, however ascertains are clearly inconsistent with claimed limitation. Applicant is directed to the recitation of "for providing continuous passive motion of a limb of a human or animal body having a torso, the limb comprising a distal end and a proximal end…" (see claim 1 lines 1-3), thereby the claimed invention clearly recites a human limb, thus the claimed invention contain non-statutory subject matter.

Applicant's argument with respect to why intended use should receive patentable weight (see remark page 6, lines 4-22) and further citing "During examination, statements in the preamble reciting the purpose or intended use of the claimed invention must be evaluated in

determine whether the recited purpose or intended use results in a structural difference (or, in the case of process claim, manipulative difference) between the claimed invention and the prior art. If so, the recitation serves to limit the clam" See MEPE 2111.02 (II) have been considered, however as stated above (see claim 1, lines 1-4) intended use recitations which Applicant argues should receive patentable weight contain non-statutory subject matters, therefore, no such structural differences are to be found, thus intended use recitation has not resulted in structural differences. Therefore, recitation of intended use cited in claim 1, lines 1-4 do not hold patentable weight.

Applicant argues that cites reference US 5,738,636 has only one control point, however US 5,738,636 disclose two control points. Applicant is directed to figure 5 where position of the actuator to control ulnar/radial deviation is considered "a first control point" (see col.6 lines 46-48) and figure 6 where position of the actuator to control pure extension and flexion motion is considered "a second control point" (see col.6 lines 48-49). Therefore, US 5,738,636 teaches two control points of the claimed invention. In further arguments Applicant states "the use of control of movement by two control points on the distal end of the limb, the control of movement being independent for both control points, allows to provide CPM exercise for separately exercising e.g. Elbow or the shoulder, without the need to exercising the other joint at the same time, which can be advantageous for medical reasons. Alternatively, however, the use of control of movement by two control points on the distal end of the limb, the control of movement being independent for both control points, allows exercising both elbow and should at the same time. The system as subject of the present invention allows to perform alternative exercises of the limb, which is not possible using the device of US 5,738,636" (see remark page 7, lines 9-17).

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., exercising both elbow and shoulder at the same time) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

For the above stated reasons Applicants arguments filed on 5/18/06 are not persuasive, therefore, former rejection presented in the office action dated 11/15/06 is maintained.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The claimed invention is directed to non-statutory subject matter. Claim 1 recites "a limb of a human or animal body having a torso, the limb comprising a distal end and a proximal end, the distal end a proximal end, the distal end being connected to the proximal end with a first joint, the proximal end being connected to the torso with a second joint." In claim 1, Applicant therefore is claiming human/animal body parts, thus the limitation of claim 1 as cited are considered non-statutory. Thus, claims 2-6,8-12, and 14-18 depending form claim 1 is also rejected under 35 U.S.C. 101.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1,3-5,9-10,and 14-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saringer et al. US Patent 5,738,636.

As to claim 1, Saringer et al. disclose a portable (web dictionary definition of portable is something capable of being transferred from one place to another; Saringer's brace is considered portable since the brace has strap members, see fig.1a reference objects 28,30, and 80 that secures the brace to a wearer so that the brace can be carried or transferred from one place to another) device suitable for providing continuous passive motion of a limb comprising (see col.1 lines 6-9): a brace (see fig.1a reference object 20) for supporting a distal end (26) (see fig.1a reference object 44, col.4 lines 44-46) of said limb; a drive mechanism (see fig.1a reference object 42) for providing a settable continuous passive motion of said limb, said drive mechanism being coupled to said brace and controlling movement of said distal end (26) of the limb characterized in that said passive motion is controlled in a first control point (see fig.5, position of the actuator to control ulnar/radial deviation is considered "a first control point", col.6 lines 46-48) and a second control point (see fig.6, position of the actuator to control pure extension and flexion motion is considered "a second control point", col.6 lines 48-49) on said distal end

(26) of said limb; and said drive mechanism comprises at least a first unit (see fig.1a reference object 70) for controlling movement of said first control point of said distal end (26) of said limb.

As to claim 3, Saringer et al. disclose a portable device according to claim 1, furthermore comprising means for immobilizing (see fig.1a reference object 48, col.4 lines 36-38) said second control point of said distal end (26) of said limb.

As to claim 4, Saringer et al. disclose a portable device according to claim 1 wherein said portable device furthermore comprises flexible positioning means (7) (see fig.1a reference object 44) provided with a fastening means (see fig.1a reference object 30) positioning said brace and said drive mechanism on the body of a patient carrying said device in a stable position (a stable position is obtained when the fastening means are used to securely position the hand/wrist relative to the body of a wearer), whereby said drive mechanism is at least partially housed (see col.4 lines 43-46) within said positioning means (7).

As to claim 5, Saringer et al. disclose a portable device according to claim 1, wherein said drive mechanism for providing a settable continuous passive motion of said limb is a motor (31) (see fig.1a reference object 42), however do not disclose a "programmable" motor in figure 1a. However, Saringer's figure 12 discloses a brace with a controller provided with an on/off button to provide an ankle (joint) movement and the range of movement (which is activated by a motor) is controlled by programming an actuator (see col7 lines 55-64). Therefore, it would have been obvious to one of ordinary skills in the art at the time the invention was made to modify the motor in figure 1a in view of figure 12 in order to include a programming motor for the purposes of limiting or controlling the range of motion of a joint (wrist).

As to claim 9, Saringer et al. disclose a potable device according to claim 1, wherein said support of the distal end (26) of the Iimb of said brace is furthermore provided with a limb fastener (10) (see fig.1a reference object 80), and said support of the proximal end (25) of the limb of said brace is furthermore provided with a Iimb fastener (10) (see fig.1a reference object 28).

As to claim 10, Saringer et al. disclose a potable device according to claim 9, wherein said fasteners for the distal end (26) and the proximal end (25) of the limb comprise fixing straps (12) (see fig.1a reference objects 80 and 28, col.4 lines 24 and 65; hook and loop type straps are considered fixing straps since they are capable of fixing the device to a wearer in a secure position).

As to claim 14, Saringer et al. disclose a portable device according to claim 4, wherein the positioning means (7) further comprises belts (see fig.1a reference object 30, a strap is considered an equivalent of a belt since they are both capable of securing the device to a body) provided with fasteners (the hook and loop, see col.4 line 24 configuration of the strap are considered fasteners), for positioning said device on a body.

As to claim 15, Saringer et al. disclose a portable device according to claim 1 further comprising a remote control unit (19) (see fig.1a reference object 56) for controlling the passive movements provided by the device

As to claim 16, Saringer et al. disclose a potable device according to claim 15, wherein said remote control unit (19) comprises control switches (see fig.1a reference object 59), however do not disclose a visual display screen, however, Saringer's figure 12 discloses a brace with a controller, more specifically a front panel which is considered "a visual display screen"

for indicating whether the user has started (as indicated by a hand symbol in fig.12) or stopped (as indicated by another symbol next to a stop label) a program for controlling a joint movement. The user depresses switch (204) to provide ankle (joint) movement and when the switch is released to stop actuator or to program the range of motion (see col7 lines 55-64). Therefore, it would have been obvious to one of ordinary skills in the art at the time the invention was made to modify the controller in figure 1a in view of figure 12 in order to include a visual display screen for the purposes of allowing the user to have a visual representation of the type of program that is being set or adjusted to limit the range of motion for a joint (wrist) movement.

As to claim 17, Saringer et al. do not disclose a potable device according to claim 1, further comprising two connectors (20) (21), provided at the upper side of the device, whereby one connector is connected to the remote control unit (19) and the other connector is connected to an electric transformer (28) or one or more batteries (27), however Saringer's fig.9 discloses two connectors (see fig.9 connectors at the upper side of reference object 180,see col.7 lines 47-54), provided at the upper side of the device, whereby one connector is connected to the remote control unit (see fig.9 a line/wire connecting one of the controller to reference object 202) and the other connector is connected to an electric transformer (see fig.1 a second line/wire connecting the other controller to a transformer, 206 via 200) or one or more batteries (see col.7 lines 50-52). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device in fig.1a in view of fig.9 in order to provide two connectors for the purposes of providing power supplies via a transformer to the control units to further control the operation of the device.

As to claim 18, Saringer et al. disclose a portable device according to claim 1, wherein the passive limb movements provided by the device are provided in an automated way (the limitation is considered an expected result of a device providing continuous passive motion. The movement is considered "automated" since it is machine driven, see col.1 lines 12-17 and col.2 lines 24-25).

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Saringer et al. US Patent 5,738,636 in view of Funk et al. US Patent 4,651,719.

As to claim 6, Saringer et al. disclose a portable device according to claim 1 wherein the brace comprises a support (see fig.1a reference object 70) for said distal end (26) of the limb comprising a first primary sub-frame (3) (see fig.1a reference object 70) for supporting said distal end (26) of the limb, a support (see fig.1a reference object 22) for said proximal end (25) of said limb comprising a second primary sub-frame (4) (see fig.1a reference object 22) for supporting said proximal end (25) of the limb, however do not disclose a hinge (5) for connecting said support for said distal end (26) of the limb to said support for said proximal end (25) of the limb. As to claim 6, Funk et al. teach a device providing a continuous passive motion to a shoulder with an upper arm support that is hinged to a base (see col.2 lines 42-49). Therefore, it would have been obvious to one of ordinary skills in the art at the time the invention was made to modify the device of Saringer et al in for the purposes of providing movement between two support members with a hinge joint as taught by Funk et al.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Saringer et al. US Patent 5,738,636 in view of Backman US Patent 5,236,411.

As to claim 8, Saringer et al. disclose a portable device according to claim 4, wherein said housing is provided with a fastening means (see fig.1a reference object 30), however do not disclose said positioning means (7) comprises an inflatable housing of flexible material provided with a fastening means, said housing allowing at least partial deformation when fastened on a body for providing a stable position. As to claim 8, Backman teaches a device for elevating a limb of a patient which comprises an inflatable member that is adjustable between a deflated state and an inflated state and a harness for attaching the device to the body of a patient. The member is placed between a support surface and the limb of a patient, thus elevating the limb (see Backman abstract). Therefore, it would have been obvious to one of ordinary skills in the art at the time the invention was made to modify the device of Saringer et al. in view of Backman in order to provide an inflatable housing for the purposes of providing adjustment and elevation of a person's limb with respect to the body.

Specification

The disclosure is objected to because of the following informalities: Applicant's specification does not specifically point out limitations of claimed invention with reference number(s) in order to describe the invention adequately and accurately. For example, claimed structures brace, first unit, second unit, triple spindle, and wheel transfer do not have corresponding reference number in the specification to distinctly point out and describe structures cited in the disclosed figure(s). Appropriate correction is required.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "brace", "first unit", "second unit", "triple spindle", "wheel transfer", and "automated way must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shumaya B. Ali whose telephone number is 571-272-6088. The examiner can normally be reached on M-F 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on 571-272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Shumaya A. 8/21/06

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Art Unit 3743

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